Negative Trend In Environmental Laboratory Data Quality

Authors

Paul Winkler, Ph.D., Mark Minteer, James Fox

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Background

- Validating environmental data for 11 years
- Nationwide client base
  - Government agencies
  - Native American tribal governments
  - Environmental engineering firms

AQA Validates Data from Numerous Laboratories

- From small labs to the largest environmental laboratories
- We have observed a general and substantial decline in data quality
- “QC only” DV, manual or automated, will not detect most of the deficiencies
- These deficiencies are often detrimental to data accuracy and defensibility

Examples

(We didn't have too look hard to find these)

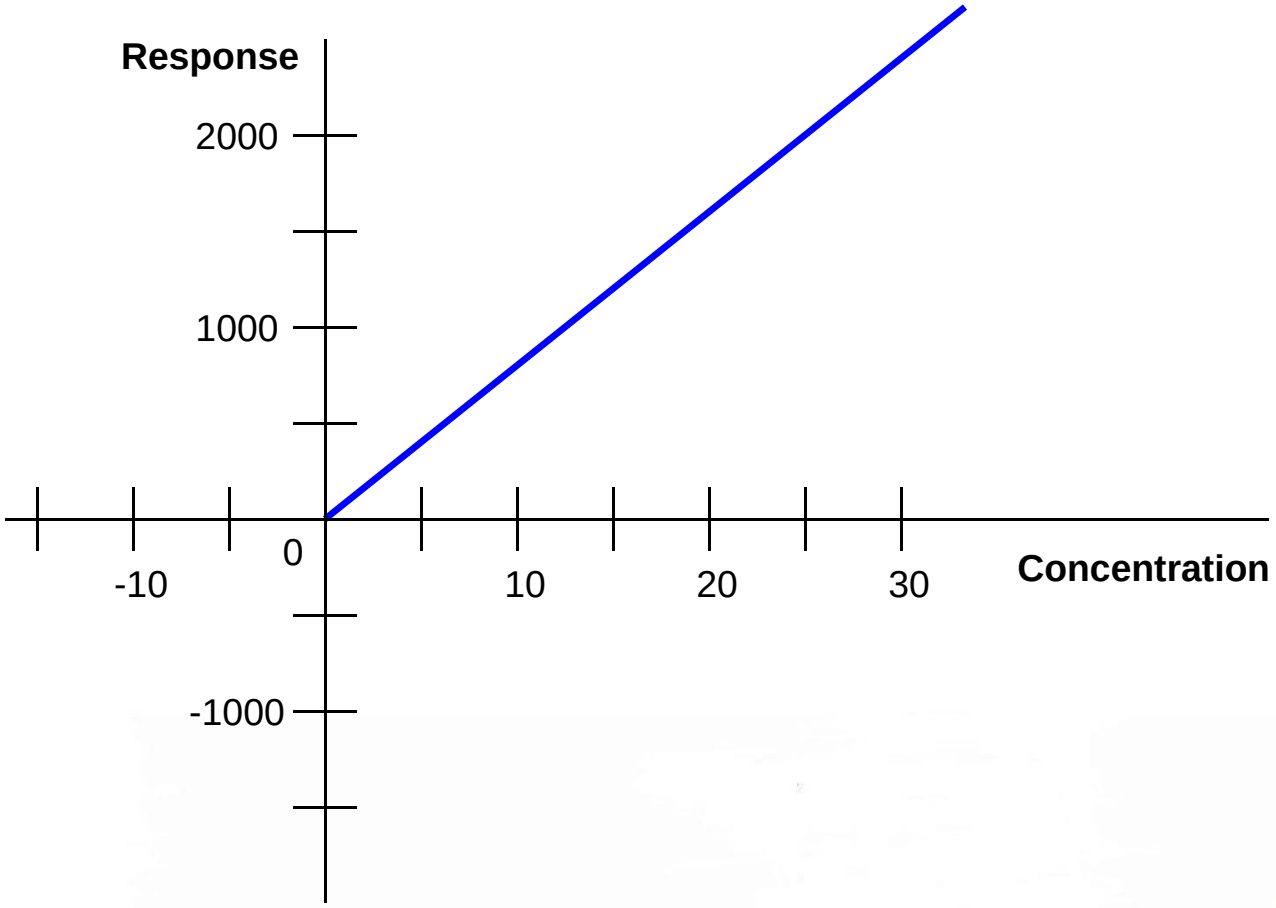
Falsification of Instrument Calibration

- Laboratory manually changed the standard areas
- Years of data affected on high-profile government project
- This problem was found by manually calculating the curve statistics from raw data
- Would not have been caught by automated data review or “QC only” data validation

Response to Average RF CAL Failure: Hide Behind a Poor Linear Fit

- Average RF calibration failed
- Resort to a linear fit (non-weighted)
- Coefficient of determination (r^2) passed
- However, concentration-intercept was unacceptably different from zero and negative (see next slide)
- Both positive and negative intercept situations often observed. Labs only look at r^2 value and not the intercept.

Small Concentrations Missed / Higher Concentrations Biased Low



Prohibited Removal of Calibration Points

- Removal of interior calibration points for acetone
- Direct violation of EPA Method 8000
- Direct violation of laboratory SOPs and ethics agreements
- All results acquired against this curve are grossly indefensible

97% Failure Rate for MS/MSD Analyses

- Method 8151
- Laboratory claimed they had adequate cleanup (GPC) capabilities
- No GPC existed
- No confidence in the reliability of the data

Analyzing QC on a Separate Instrument

- Defeats the several key goals of QC. For example, MB analysis will indicate contamination of prep and instrument. LCS is used to measure control of entire analytical process, not just extraction.
- Laboratory returned to same practice after being notified it was not acceptable
- Whether a time-saver or malicious, severely hampers defensibility of data.
- Dramatically increases data validation labor and costs

Some Other Examples

- Unreported positive hits
- Misreported QC recoveries
- Multiple manual integrations to make QC pass
- Misused/overused “matrix effects” assertions
- Failure to perform required re-analyses
- Rampant QC/IS/surrogate failures
- Failure to maintain certifications
- Failure to perform blank population MDCs

What's Causing This Decline?

Largely Attributable to Lowest Price — Technically Acceptable (LPTA) Contracting

Problems with LPTA

- Failure to adequately determine Technical Acceptance
- Deviation from Best Value approach to contracting
- Price becomes only concern, there is a perfunctory nod to actual quality, not a real inquiry

Effects of LPTA on Laboratory Operations (1)

- You are not the lowest bidder, you lose!
- You must trim laboratory operations so you can be the low bidder

Effects of LPTA on Laboratory Operations (2)

- Increased laboratory burden
  - Decreased per sample price / increased number of samples to generate same revenue
  - Analytical shortcuts
- Eroded management commitment to quality
- Decreased quality assurance oversight
- Deliverable corrections and CAR responses not delivered in a timely manner

What is Technically Acceptable?

- Laboratory scope and capacity
- Proper equipment
- Qualified personnel
- Quality systems
- Reporting capability
- Track record of compliant on-time performance

How is Technical Acceptability Typically Verified?

- Review of laboratory proposals only (no pre-qualification audit)
- Pre-qualification audits by QA officers only
- Sending technical staff who are not experienced analytical chemists
- Reliable verification is accomplished via a pre-qualification audit performed by experienced analytical chemist(s)

Common Misconceptions

- Laboratory certifications guarantee a technically qualified lab
  - Implementation of a standard is only as good as the personnel implementing it
  - AQA has observed serious failures by certified laboratories
- Information supplied by laboratories is comprehensive and accurate
  - Laboratory assertions are often misleading at best

Consequences of Inadequate Verification

- Acquisition of indefensible data
- Misleading data such as false positives or false negatives
- Diminished quality (excessive qualification)
- Contracts awarded to laboratories that do not have sufficient capacity to generate compliant data on-time

Summary

- Overall decline in environmental laboratory data quality
- LPTA contracting, to a substantial degree, is a root cause of the declining quality
- Meaningful technical acceptability verification needed
- Problems presented are the tip of the iceberg
- Problems won't be found using automated data validation software or cursory "QC Only" data validation